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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,155	06/22/2006	Hideki Ohyama	Q95616	5059

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EXAMINER	
POLANSKY, GREGG	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,155	OHYAMA, HIDEKI	
	Examiner	Art Unit	
	Gregg Polansky	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-4 are pending.

Specification

3. The use of the following trademarks have been noted in this application: Myocalm® and Priscol®. They should be written in all capital letters wherever they appear; or alternatively, they should be denoted with the registered trademark symbol, ®, and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Objections

4. Claim 3 is objected to for the following informalities: the current wording is awkward and either technically or grammatically incorrect. In light of the specification, the Examiner interprets this claim as a method for treating severe aphasia in a patient who has been diagnosed as having the severe aphasia as a consequence of chronic stage cerebrovascular accident. The Applicant is advised to amend the claim.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 3 discloses "a dose of from 9 to 40 g/day **for a long term of 2 months or more**". The emphasized phrase does not adaquetly define the metes and bounds of the claim. "A long term" is an awkward phrase of indefinite meaning and "2 months or more" fails to define an upper limit for treatment.

Claim 4 provides for the "use of 2-oxo-1-pyrrolidineacetamide for the manufacture of an agent for treating aphasia in cerebrovascular accident chronic stage", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 4 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber (Pharmacopsychiatry, 1999).

Huber teaches the administration of 2-oxo-1-pyrrolidineacetamide (piracetam) in the treatment of acute and chronic aphasia following stroke. [Stroke is also known as a cerebrovascular accident (*see* 1st paragraph of Dudley, Alden. W. "Stroke." *Grolier Multimedia Encyclopedia*. Grolier Online http://gme.grolier.com/cgi-bin/article?assetid=0278580-0 (accessed August 2, 2007))]. A study cited by Huber demonstrates that in patients suffering with post-acute and chronic aphasia (aphasia up to 3 years after stroke), improvement in speech occurred as a result of piracetam treatment (*see* Abstract).

Therefore, Claims 1, 2, and 4 are fully anticipated by Huber and are properly rejected.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huber (Pharmacopsychiatry, 1999).

In addition to the teachings by Huber, presented in support of the rejection of Claims 1, 2, and 4 under 35 USC § 102 section (*supra*), the reference also teaches that the dose of piracetam used in the post-acute and chronic aphasia study was 4.8 g/day for 6 weeks (*see* page 39, Table 2, 1st study).

Huber does not teach a dose of piracetam within the dose range disclosed in instant Claim 3 (i.e., 9-40 g/day, for 2 months or more). Additionally, Huber does not teach that the chronic aphasia patients in the study had "no expectation of improvement" as also required by Claim 3.

Although Huber does not teach a dose of piracetam within the dose range disclosed in instant Claim 3, he does teach a dose of 12 g/day (which is within the disclosed dose range) in an acute aphasia study. However, one of ordinary skill in the art (e.g. a medical doctor or person possessing a PhD in pharmacology or pharmacy) would use the doses and durations of treatment disclosed in the prior art as only a

starting point for determining the most effective dose and length of treatment with piracetam, in view of an individual patient's clinical profile. Generally, differences in, for example, concentration or temperature, will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.").

Finally, although Huber does not teach that the chronic aphasia patients in the study had "no expectation of improvement", however The Merck Manual teaches that "any deficit remaining after 6 mo[nths] is likely to be peranent" (*see* page 1422, 2nd column, "Prognosis"). One skilled in the art could reasonably expect that individuals afflicted with stroke-induced aphasia, lasting for multiple years, would have no reasonable expectation of improving.

Therefore, a skilled artisan at time of the instant invention, would have been motivated to use the teachings of Huber as a guide for the treatment of stroke-induced chronic aphasia, and to use his/her knowledge and inventiveness to improve upon these methods (e.g., modify treatment dose, frequency, and schedule), to provide for an improved patient prognosis.

Conclusion

13. Claims 1-4 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GP

Phyllis Spivack 8/13/07

PHYLLIS SPIVACK
PRIMARY EXAMINER